

Patient package insert in accordance with the Pharmacists' Regulations (Preparations) -

1986

The dispensing of this medicine requires a doctor's prescription

Pregabalin Taro 75 mg

Pregabalin Taro 100 mg

Pregabalin Taro 150 mg

Pregabalin Taro 200 mg

Pregabalin Taro 225 mg

Pregabalin Taro 300 mg

Capsules

Pregabalin 75, 100, 150, 200, 225, 300 mg

Inactive ingredients and allergens: see Section 2 under 'Important information about some of this medicine's ingredients' and Section 6 'Additional information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed to treat you, do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for treating children and adolescent under 18 years old.

1. What is this medicine intended for?

For treatment of neuropathic (neural) pain in adults, for treatment of fibromyalgia, and for treatment of generalized anxiety disorder (GAD) in adults.

Therapeutic group:

A gamma-aminobutyric acid analog.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (listed in Section 6).

Special warnings regarding the use of the medicine

Contact your doctor before taking the medicine

- Some patients taking Pregabalin Taro have reported allergic effects. These effects include swelling in the face, lips, tongue, and throat, as well as diffuse skin rash. If you experience one or more of these effects, refer to a doctor immediately.
- The medicine may cause dizziness and somnolence, so elderly patients taking this medicine are at increased risk of falls and injuries. Use with caution until you get used to the medicine's effect on you.
- This medicine may cause blurring or loss of vision, or other changes in vision, most of which are transient - inform the doctor immediately of any change in your vision.

- In some patients with diabetes, who gain weight while taking this medicine, the dosage of medicines for lowering blood sugar level may have to be adjusted.
- Certain side effects, such as sleepiness, may be more common, because patients with spinal injury may be taking other medicines to treat pain and spasticity, that have side effects similar to those of Pregabalin Taro and their severity may increase when these are taken together.
- Heart failure has been reported in a number of patients who took this medicine, mostly in elderly patients with cardiovascular diseases. **Before you start taking this medicine tell your doctor if you have ever had heart disease.**
- Several cases of kidney failure associated with treatment with this medicine have been reported. If you notice decreased urination during treatment with this medicine, inform the doctor, as discontinuing treatment with this medicine may bring an improvement.
- Suicidal thoughts or suicidal behavior have been reported in a small number of patients who were treated with antiepileptic medicines such as Pregabalin Taro. You and your family members should pay attention to any changes in mood and behavior patterns. If this sort of thoughts occur at any point, refer to the doctor immediately.
- Combining Pregabalin Taro with other medicines (e.g., certain types of analgesics), which might cause constipation, may cause gastrointestinal problems (e.g. constipation, blocked or paralyzed bowel). Inform your doctor if you are constipated, particularly if you are prone to constipation.
- Before you start taking the medicine, inform the doctor if you are suffering, or have suffered in the past, from addiction to or dependence on alcoholic beverages, drugs or any medicines. Do not take a higher dosage than that which has been prescribed for you.
- Convulsions may occur during treatment with the medicine or immediately after stopping it - inform the doctor immediately if you are having convulsions.
- Reduced brain function (encephalopathy) has been reported in a number of patients with other underlying conditions. Inform the doctor if you have a history of any medical condition with serious implications, including liver or kidney disease.
- There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, or you are older than 65, your doctor may prescribe you a different dosing regimen. Consult your doctor if you experience difficulty breathing or shallow breaths.

Other medicines and Pregabalin Taro

If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements, tell your doctor or pharmacist. Particularly if you are taking:

Pregabalin Taro and certain other medicines may have reciprocal effects on medicine activity.

If Pregabalin Taro is taken together with certain medicines which have sedative effects (including opioids), it may potentiate these effects and could lead to respiratory failure, coma, and death. Intensity of dizziness, sleepiness, and reduced concentration may increase if Pregabalin Taro is taken concomitantly with:

Oxycodone - a pain-relief medicine.

Lorazepam - a medicine for treating anxiety.

Alcohol.

Pregabalin Taro may be taken with contraceptive pills.

Using the medicine and food

This medicine can be taken without regard to meals.

Using the medicine and alcohol consumption

Do not consume alcohol during the treatment with this medicine.

Pregnancy, breastfeeding, and fertility

Do not use Pregabalin Taro during pregnancy or breastfeeding, unless your doctor has instructed you to do so after consultation.

Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. In a study reviewing data from women in Nordic countries who took pregabalin in the first 3 months of pregnancy, 6 in 100 babies had such birth defects. This compares to 4 in 100 babies born to women not treated with pregabalin in the study. Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Women who may become pregnant during the treatment with this medicine must use effective contraceptives.

Consult a doctor or pharmacist before using this medicine if you are pregnant or breastfeeding, if you suspect that you are pregnant or you are planning to become pregnant.

Driving and using machines

Do not drive or operate dangerous machines until you know how this medicine affects you, because using this medicine may cause dizziness, drowsiness or decreased concentration.

Important information about some of this medicine's ingredients

This medicine contains lactose monohydrate. If you have been told by your doctor that you are intolerant to certain sugars, consult your doctor before you start taking this medicine.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dose or about how to take this medicine.

Do not exceed the recommended dose!

Swallow the capsule whole. Do not open the capsule and disperse its contents because this method of administration has not been tested. Swallow the medicine with water.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, see a doctor immediately or go immediately to a hospital emergency room and bring the medicine package with you. You may feel drowsy, confused, worried, or restless from taking an overdose of Pregabalin Taro. Fits (convulsions) have also been reported.

If you forget to take the medicine at the scheduled time

It is important to take this medicine at the same time every day. If you forget to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.**If you stop taking this medicine**

Even if your health improves, do not stop taking this medicine without consulting your doctor. If a decision is made to stop treatment, treatment with this medicine must be stopped gradually over a period of at least a week.

After stopping this medicine (after long-term or short-term treatment), you may experience: insomnia, headaches, nausea, anxiety, flu-like symptoms, convulsions, nervousness, depression, pain, dizziness, sweating and diarrhea. These symptoms may occur more commonly and severely if the medicine has been taken for a longer period of time.

Do not take medicines in the dark! Check the label and dose each time you take the medicine.

Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, taking Pregabalin Taro may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

Refer to a doctor immediately if you experience swelling of the face or the tongue, or a severe skin reaction (the skin reddens and becomes covered with blisters or peels).

Very common side effects: affect more than 1 in 10 people

- dizziness, drowsiness, headaches.

Common side effects: affect up to 1 in 10 people

- increased appetite.
- feeling of elation, confusion, disorientation, reduced sex drive, irritability, clumsiness.
- concentration or memory impairment, memory loss, tremor, difficulty speaking, tingling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.
- blurred vision, double vision.
- vertigo, balance disorders, falls.
- dry mouth, constipation, vomiting, flatulence, diarrhea, nausea, swollen abdomen.
- erection problems.
- swelling of the body including extremities.
- feeling drunk, abnormal style of walking.
- weight gain.
- muscle cramps, joint pain, back and limb pain.
- sore throat.

Uncommon side effects: affect up to 1 in 100 people

- loss of appetite, weight loss, decreased blood sugar level, increased blood sugar level.
- change in self-perception, restlessness, depression, anxiety, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attacks, apathy, aggression, elevated mood, mental disorder, difficulty thinking, increased sex drive, problems with sexual functioning, delayed ejaculation.
- vision changes including loss of peripheral vision, jittery eye movement, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness when standing up, skin sensitivity, loss of taste, burning sensation, tremor when moving, reduced consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- dry eyes, eye swelling or pain, weak eyes, watery eyes, eye irritation.
- heart rhythm disturbances, increased heart rate, low or high blood pressure, changes in heart-beat, heart failure.
- flushing, hot flushes.
- difficulty breathing, dry nose, nasal congestion.
- increased saliva production, heartburn, numbness around the mouth.
- sweating, rash, chills, fever.
- muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- breast pain.
- difficulty with or painful urination, urinary incontinence.
- weakness, thirst, chest tightness.
- changes in blood and liver test results (increase in blood creatine phosphokinase, increased liver enzymes, decreased platelet count, neutropenia, increase in blood creatinine, decrease in blood potassium).
- hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.
- painful menstrual periods.
- cold hands and feet.

Rare side effects: affect up to 1 in 1,000 people

- abnormal sense of smell, fluctuations in vision, change in depth perception, visual brightness, vision loss.
- dilated pupils, cross eyes.
- cold sweat, irritation of the throat, swollen tongue.
- inflammation of the pancreas.
- difficulty in swallowing.
- slower or reduced movement of the body.
- difficulty with writing.
- edema in the abdominal area.
- fluid in the lungs.
- convulsions.
- changes in ECG which correspond with heart rhythm disorders.
- muscle damage.
- breast discharge, abnormal breast growth, breast growth in men.
- menstrual cycle disorders.
- kidney failure, reduced urine volume, urinary retention.

- decrease in white blood cell count in blood test.
- abnormal behavior.
- allergic reactions (may manifest as: breathing difficulties, inflammation of the eyes [keratitis] and a serious skin reaction characterized by rash, blisters, peeling skin and pain).
- jaundice (yellowing of the skin and whites of the eyes).
- parkinsonism, that is symptoms resembling Parkinson's disease such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness).

Very rare side effects: affect up to 1 in 10,000 people

- liver failure.
- inflammation of the liver (hepatitis).

Certain side effects, such as sleepiness, may be more common, because patients with spinal injury may be taking other medicines to treat pain and spasticity, that have side effects similar to those of Pregabalin Taro and their severity may be increased when taken together.

The following side effects have been reported post-marketing: difficulty breathing and shallow breaths.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects, or by clicking the link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C.

6. Additional information

In addition to the active ingredient this medicine also contains:

maize starch, lactose monohydrate, talc, titanium dioxide, gelatin, black iron oxide, shellac, propylene glycol, potassium hydroxide.

Pregabalin Taro capsules 75 mg, 100 mg, 200 mg, 225 mg, and 300 mg also contain: red iron oxide.

Pregabalin Taro capsules 200 mg, and 225 mg also contain: yellow iron oxide.

This medicine contains lactose monohydrate:

Pregabalin Taro 75 mg: 8.25 mg lactose monohydrate, Pregabalin Taro 100 mg: 11.00 mg lactose monohydrate, Pregabalin Taro 150 mg: 16.50 mg lactose monohydrate, Pregabalin Taro 200 mg: 22 mg lactose monohydrate, Pregabalin Taro 225 mg: 24.75 mg lactose monohydrate, Pregabalin Taro 300 mg: 33 mg lactose monohydrate.

What the medicine looks like and contents of the pack:

Pregabalin Taro 75 mg: a white capsule with a brown-red cap. The number “75” is imprinted in black on the capsule body.

Pregabalin Taro 100 mg: a brown-red capsule with a brown-red cap. The number “100” is imprinted in black on the capsule body.

Pregabalin Taro 150 mg: a white capsule with a white cap. The number “150” is imprinted in black on the capsule body.

Pregabalin Taro 200 mg: a pink-orange capsule with a pink-orange cap. The number “200” is imprinted in black on the capsule body.

Pregabalin Taro 225 mg: a white capsule with a pink-orange cap. The number “225” is imprinted in black on the capsule body.

Pregabalin Taro 300 mg: a white capsule with a brown-red cap. The number “300” is imprinted in black on the capsule body.

This medicine is supplied in packs of 14, 28, 56 capsules.
Not all pack sizes may be marketed.

Manufacturer: Sofarimex – Industria Quimica e Farmaceutica, S.A, Cacem, Portugal

Registration holder: Taro International Ltd., 14 Hakitor St., Haifa Bay
2624761

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Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:

Pregabalin Taro 75 mg: 158-25-34763

Pregabalin Taro 100 mg: 158-26-34762

Pregabalin Taro 150 mg: 158-27-34761

Pregabalin Taro 200 mg: 158-28-34760

Pregabalin Taro 225 mg: 158-29-34759

Pregabalin Taro 300 mg: 158-30-34740